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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John W. Hadden

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EXAMINER

WEN, SHARON X

ART UNIT

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1644

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,320	Applicant(s) HADDEN, JOHN W.	
	Examiner SHARON WEN	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26, 28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 12, 13, 17-23 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-16, 24, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 07/15/2008, has been entered.
Claims 25, 27 and 29 have been **canceled**.
Claims 1-24, 26, 28 and 30-32 are **pending**.
2. Regarding nonelected / withdrawn claims, the following is noted.
Currently amended claims 12-13 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
The originally elected Invention was drawn to a method of immunotherapy comprising administering a natural cytokine mixture and the originally elected species of the method was administering the NCM with cyclophosphamide (CY) and a nonsteroidal anti-inflammatory drug (NSAID) (see Response to Election / Restriction, filed 11/26/2007). The amended claims 12 and 13 are now drawn to a method of immunotherapy to treat cancer consisting of administering CY and indomethacin (INDO) only without NCM, which is patentably distinct from the originally elected Invention/species.
Since applicant has received an action on the merits for the originally elected Invention/species, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-13 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
Therefore, claims 12-13 along with 17-23 and 30-32 are **withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions/species.
3. Claims 1-11, 14-16, 24, 26 and 28 are **currently under examination** as they read on a method of immunotherapy to treat head and neck squamous cell carcinoma (H&NSCC) by administering a natural cytokine mixture (NCM).

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4. This Action will be in response to Applicant's Arguments/Remarks, filed 07/15/2008.

The rejections of record can be found in the previous Office Action.

Priority

5. In response to Applicant's amendment to the claims, changing "interferon-delta (IFN- δ)" to "interferon-gamma (IFN- γ)", the following is noted.

It is noted that the IFN- γ disclosed in the application, specifically on Table 1, page 26, support the change. In view of the Applicant's amendment to the claims to change "interferon-delta (IFN- δ)" to "interferon-gamma (IFN- γ)", the priority issue raised in the previous Office Action, mailed 02/20/2008, has been resolved. Therefore, the priority date for claims 1-11, 14-16, 24, 26 and 28 is deemed the effective filing date of the provisional application, USSN 60/243,912, i.e., 10/27/2000.

6. However, in response to Applicant's assertion that "*one skilled in the art would automatically recognize*" that "interferon-delta (IFN- δ)" is a typographical error because there is no such compound that exist called IFN- δ in humans, the following is noted.

The claims, filed 02/07/2006, were directed to a treatment method by administering a natural cytokine mixture (NCM) comprising IFN- δ . The definition of NCM provided by the specification as-filed, is as follows:

By "NCM," it is meant as a natural cytokine mixture, as defined and set forth in U.S. Pat. Nos. 5,632,983 and 5,698,194. The NCM can include recombinant cytokines. Briefly, NCM is prepared in the continuous presence of a 4-aminoquinolone antibiotic and with the continuous or pulsed presence of a mitogen, which in the preferred embodiment is PHA. (see page 7 lines 18-22.)

It is noted that the above mentioned patents 5,632,983 and 5,698,194 give similar description of the NCM and do not require the cytokines to be from human.

According to the above description, the cytokines used in the claimed method are not required to be from human. Therefore, the recited IFN- δ does not have to be made by the process pointed out by the Applicant in paragraphs [0094] and [0095], especially

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given the open language of the claims, i.e., "a natural cytokine mixture (NCM) **including** cytokines selected from the group **consisting essentially of** IL-1, IL-2, IL-6, IL-8, IL-12, IFN-6, TNF-a, GM-CSF, G-CSF, recombinants thereof, and combinations thereof."

Therefore, Applicant's argument that IFN- δ is an obvious typographical error because IFN- δ does not exist in human has not been found convincing because the claimed method does not require the recited IFN- δ to be from human.

Furthermore, IFN- δ has been known to be used in cancer treatment as evidenced by Rees et al. (US 20030007955 A1, reference of record, see previous Office Action, mailed 02/20/2008). Therefore, one of skill in the art would not have automatically recognized that the recited IFN- δ is a typographical error.

Sequence Compliance

7. The present application stands objected to for failure to comply with sequence rules. Applicant is directed to notice of **Computer Readable Form (CRF) for Sequence Listing – Defective**, mailed 07/21/2008.

Claim Rejections - 35 USC § 112 second paragraph

8. Upon further consideration, the previous rejection under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of Applicant's remarks, filed 07/15/2008.

Claim Rejections - 35 USC § 112 first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for eliciting an immune response to exogenous tumor antigen comprising administering an effective amount of exogenous tumor antigen and NCM, does not reasonably provide enablement for a method of immunotherapy to treat

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cancer comprising administering an effective amount of NCM without exogenous tumor antigen, while allowing presentation by mature dendritic cells of exogenous antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The New Grounds of Rejection herein are necessitated by Applicant's amendment to the claims, filed 07/15/2008.

Claims 1-11 are drawn to a method of treating cancer comprising administering a natural cytokine mixture (NCM). The claims do not require administering any exogenous antigen, but the claims do require maturing immature dendritic cells and presentation of exogenous antigens by the mature dendritic cells.

The specification is enabled for eliciting an immune response to exogenous tumor antigen comprising administering an effective amount of exogenous tumor antigen and NCM (see, e.g., page 11 last paragraph). However, the specification, as-filed, is not enabled for presentation of exogenous antigens by the mature dendritic cells without administering any exogenous antigen, especially the dendritic cells were immature (i.e., have not been stimulated by antigen) to start with, as claims suggest.

A person of ordinary skill was well-aware at the time of the invention was made that antigen is needed to elicit an immune response to the antigen. For example, Janeway et al. teach that the fundamental induction of an immune response, known as immunization, is routinely performed in experiments by injecting the test antigen into animal or human subjects (see *ImmunoBiology: the Immune System in Health and Disease*, 3rd edition, 1997, Current Biology Ltd., London, UK and Garland Publishing Inc., New York, NY, USA. Page 2:2).

The instant specification discloses that that NCM is used as an adjuvant in addition to exogenous tumor antigens to immunize cancer patient against tumor antigens (see page 18, lines 28-30 and page 20, lines 29-31). In addition, the specification discloses examples of eliciting delayed type hypersensitivity in mice and human by administering specific cancer antigens in conjunction with NCM, CY and INDO as adjuvant (see pages 43-44, Example 12). The specification does not provide

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sufficient *in vivo* or *in vitro* evidence showing administering NCM, CY and/or INDO without any exogenous tumor antigen would elicit an immune response to any exogenous tumor antigen.

The instant application provides insufficient guidance and instruction on the necessary steps one of skill would need to administer the adjuvant (i.e., NCM, CY and/or INDO) without any exogenous tumor antigen and achieve the intended results, i.e. elicit an immune response against exogenous tumor antigens. In view of the unpredictability of the art and insufficient working examples provided by Applicant, it would require undue amount of experimentation for a skilled artisan to practice the claimed invention.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant is invited to amend the claims by reciting an administering step comprising administering an exogenous tumor antigens similar to the amendment in claims 24, 26 and 28.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. In view of Applicant's amendment to the claims, the previous rejections under 35 USC 102(b) as anticipated by Meneses et al. (reference of record) has been **withdrawn** for claims 24, 26 and 28.

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13. Claims 1-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Meneses et al. (*Arch. Pathol. Lab. Med.* 1998, 122:447-454, reference of record, see entire document).

It is noted that the prior art was not previously applied to claims 14-16. However, given Applicant's amendment to the claims (i.e., changing "interferon-delta (IFN- δ)" to "interferon-gamma (IFN- γ)"), this rejection is set forth herein for reasons of record as stated in the previous Office Action, mailed 02/20/2008.

Meneses et al. teach a method of treating head and neck squamous cell carcinoma (H&NSCC) comprising administering a NCM comprising IL-1, IL-2, IL-6, IL-8, IL-10, IL-12, TNF- α , colony stimulating factor (CSF), interferon gamma (IFN- γ) and effective amounts of CY and INDO, in which 150 units of IL-2 equivalence by ELISA is administered, specifically (see, e.g., page 447, Abstract "**Patients**" and page 448, Material and Methods, "**Natural Cytokine Mixture**" and "**IRX-2 Treatment Schedule**"). In addition, the administration is prior to surgery and during recurrence and both unilaterally and bilaterally for cases of midline lesions (see pages 448-449 "**IRX-2 Treatment Schedule**").

The prior art also teaches recombinant IL-2 used in treatment (see page 447, last paragraph). It is noted that the recitation of "recombinant" in the present claim is a product-by-process limitation which reads on the cytokine that is made by a recombinant process. Since the reference teaches the cytokines of the present invention, the same cytokines made by a recombinant process would also be anticipated by the reference.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It is also noted that although the prior art does not explicitly teach "a synergistic anti-cancer treatment that produces an activity greater than the individual activities of

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the NCM, CY and INDO" *per se*, given the same or nearly the same method step of administering a NCM plus CY and INDO for treating H&NSCC; and that the present claims do not recite any particular dosage that contributes to the synergistic effect; it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories* 58 USPQ2d 1508 (CAFC 2001).

Under the broadest reasonable interpretation of claims 1-11, the recited method does not require a step of administering an exogenous antigen. Therefore, the prior art meets the claim in administering NCM.

Regarding the above enablement of *presentation of antigen by dendritic cells without administering an antigen*, it is noted that "the standard for enablement of a prior art reference for purposes of anticipation under section 102 differs from the enablement standard under 35 USC § 112" and that "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art." (See, *Impax Laboratories Inc.*, 81 U.S.P.Q.2d 1001, 1012, citing *Novo Nordisk Pharms., Inc v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)).

Moreover, given that the prior art teaches administering NCM to patients with recurrent tumors, the presence of immature dendritic cells would be an inherent characterization of administering NCM to these patients. Therefore, maturing immature dendritic cells and allowing presentation of the resulting mature dendritic cells to present tumor antigens would be an inherent property of administering a NCM as taught by the prior art.

In response to Applicant's argument that the prior art does not teach the key mechanistic feature of the present invention (i.e., in vivo maturation of dendritic cells resulting in effective antigen presentation), Applicant is reminded that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). Given that the prior art teaches the same or

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nearly the same method of immunotherapy to treat cancer by administering a NCM, CY and INDO, the mechanistic features would be would be inherent properties of the taught method.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The previous rejection under 35 U.S.C. 103(a) as being obvious over Meneses et al. (*Arch. Pathol. Lab. Med.* 1998, 122:447-454) in view of Rees et al. (US 20030007955 A1) has been **withdrawn** in view of Applicant's amendment to the claims, i.e., changing "interferon-delta (IFN- δ)" to "interferon-gamma (IFN- γ)", filed 07/15/2008.

16. Claims 1-11, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being as being obvious over Meneses et al. (*Arch. Pathol. Lab. Med.* 1998, reference of record, 122:447-454) in view of Weiner et al. (PNAS 1997, 94:10833-10837).

The New Grounds of Rejection set forth herein are necessitated by Applicant's amendment.

The teaching by Meneses et al. has been discussed supra.

In addition to the teaching by Meneses et al. discussed supra, Meneses et al teach a method of treating head and neck squamous cell carcinoma (H&NSCC) comprising administering a NCM comprising IL-1, IL-2, IL-6, IL-8, IL-10, IL-12, TNF- α , colony stimulating factor (CSF), interferon gamma (IFN- γ) and effective amounts of CY and INDO, in which 150 units of IL-2 equivalence by ELISA is administered, specifically (see, e.g., page 447, Abstract "**Patients**" and page 448, Material and Methods, "**Natural Cytokine Mixture**" and "**IRX-2 Treatment Schedule**"). In addition, the administration is

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prior to surgery and during recurrence and both unilaterally and bilaterally for cases of midline lesions (see pages 448-449 “**IRX-2 Treatment Schedule**”).

Meneses et al. do not teach further administering a tumor antigen. However, administration of exogenous tumor antigen as part of anti-cancer immunotherapy was well known in the art at the time of the invention as evidenced by Weiner et al. (see entire document). In particular, Weiner et al. teach administering tumor specific antigens along with immune adjuvants to activate immune cells such as dendritic cells in the immunization against tumor growth (see e.g., Abstract).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to include an administering step comprising a tumor antigen in the immunotherapy for treating head and neck squamous cell carcinoma as taught by Meneses et al. because tumor specific antigens and the treatment including them were well known in the art at the time.

Given that the claimed elements (NCM, CY, INDO and exogenous tumor antigen) were known in the prior art and one of ordinary skill in the art could arrive at the claimed invention by using known methods (administering to tumor patients as taught by Meneses) with no change in their respective functions, the combination would have yielded nothing more than predictable results of anti-cancer immunotherapy against head and neck squamous cell carcinoma. Therefore, it is obvious to combine prior art elements according to the known methods to yield predictable results.

Furthermore, one ordinary skill in the art would have been motivated to include the tumor antigen in the treatment because Weiner et al teach that immunization with tumor specific antigens and immune adjuvants such as cytokines can induce the orchestrated activation of various immune subsets and the production of multiple cytokines known to participate in the development of an active immune response that is likely to be more effective and perhaps less toxic than immunization using single cytokine as an adjuvant (see paragraph bridging pages 10835-10836).

In conclusion, given that the Meneses et al. teach the claims at immunotherapy comprising administering NCM, CY and INDO to patients with H&NSCC and Weiner teach that using a tumor specific antigen along with immune adjuvants such as

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cytokines would be beneficial for anti-cancer immunotherapy, it would have been obvious to one of skill in the art at the time of the invention to achieve the predictable results of immunotherapy to treat H&NSCC.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-2, 10-11, 14-16, 24, 26 and 28 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9 of U.S. Patent No. 6,977,072 ('072). Although the conflicting claims are not identical, given that both sets of claims are drawn to the same or nearly the same method of treating cancer comprising administering NCM, CY and INDO, they are not patentably distinct from each for reasons of record.

Applicant's willingness to provide the appropriate terminal disclaimer upon allowance of the pending claims has been acknowledged. However, the present claims stand rejected for reasons of record.

Applicant is reminded this rejection is not *provisional* as Applicant asserted in the Arguments / Remarks, file 07/15/2008.

19. Claims 1-11, 14-16, 24, 26 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the following:

A) claims 1-4, 7-11, 13-18, 20-39 and 45 of copending application USSN 11/582,063;

B) claims 28-53 of copending application USSN 11/374,783;

C) claims 38-46 and 52-62 of copending application USSN 11/337,358; and

D) claims 1-4, 7-11, 13-18, 20-23 and 25-31 of copending application USSN 11/006,451.

F) claims 17-46 of copending application USSN 11/492,418.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the above mentioned claims of the co-pending applications and the claims of the present application are drawn to a method of eliciting an immune response to an antigen comprising administering NCM, CY, INDO. Given the same or nearly the same method steps recited in these sets of claims, they would have anticipated or rendered obvious one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that the previous Office Action was mailed before the above mentioned claims of the copending applications were made available to the Examiner, the new grounds of rejection are set forth herein.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

October 7, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644

/JOHN L. LEGUYADER/

Director, Technology Center 1600